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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,505	12/28/2001	Aaron J. Swanson	047711-0294	1237

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EXAMINER

CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/034,505	Applicant(s) SWANSON ET AL.	
	Examiner MONZER R CHORBAJI	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☒ Claim(s) 37-44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/17/03 & 2/25/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 30 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 30, lines 1-2; applicant uses the term "a sensor matrix protein". The specification does not explain what is the meaning of a sensor matrix protein.

Clarification is needed to understand the meaning of such a term.

In claim 36, line 3; applicant uses the term "preparing". The specification does not explain the meaning of "preparing". Clarification is needed to understand the meaning of such a term.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 5-9, 11, 14, 19 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipate by Odland (U.S.P.N. 5,989,498).

With respect to claims 1, 14 and 23, the ('498) reference teaches a sterile apparatus (col.5, lines30-32) and a method (abstract, lines 1-10) for sterilizing such an apparatus including the following: a sterile buffer (col.7, lines 4-10), a sterile device immersed in the buffer and a sterile package that encloses both the device and the buffer (col.5, lines 20-22).

With respect to claims 2, 5-9, 11, 19 and 24, the ('498) reference discloses the following: medical device is implantable (col.5, lines 30-32), transparent (inherent in order to sterilize the device within the package) and translucent sterile package (inherent in order to sterilize the device within the package), sterile package is optically transmissive (inherent in order to sterilize the device within the package), buffer and package have been sterilized using light (col.5, lines 30-32), packaging the apparatus in a bicarbonate solution (col.7, lines 14-15) and sterile device includes a liquid-sterilized device (col.5, lines 30-32).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3-4, 10, 12-13, 15, 18, 20-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Odland (U.S.P.N. 5,989,498) in view of Clark, Jr. (U.S.P.N. 4,680,268).

The teachings of the ('498) reference have previously been set forth with respect to claims 1-2, 5-9, 11, 14, 19 and 23-24. With respect to claims 3-4, 10, 12-13, 15, 18, 20-22 and 25, the ('498) fails to teach the following: the use of a hydrated sensor, sterilizing by gas, the use of a biomolecule and the use of glucose oxidase as a biomolecule, however, the ('268) reference, which is in the art of implanting sterilized biosensors, teaches the following: the use of a hydrated sensor (col.13, lines 48-50), sterilizing by gas (col.13, lines 34-36) and the use of a biomolecules such as glucose oxidase (col.10, lines 32-35). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus and the

method of the ('498) to include sterilizing implantable biosensors as taught by the ('268) reference since new implantable devices, and methods are needed for the measurement, administration and regulation of key biological substances, such as blood glucose and insulin (col.3, lines 27-30).

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Odland (U.S.P.N. 5,989,498) in view of Clark et al (U.S.P.N. 5,925,885).

The teachings of the ('498) reference have previously been set forth with respect to claims 1-2, 5-9, 11, 14, 19 and 23-24, however; with respect to claim 16, the ('498) reference fails to teach the use of a broad- spectrum pulse light. The ('558) reference, which is in the art of sterilizing medical devices, teaches using a broad-spectrum pulse light (col.3, lines 65-67). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the ('498) reference by substituting the broad-spectrum pulse light for the electron beam light as taught by the ('885) since such a light does not degrade the polyolefin packaging material (col.9, lines 34-38).

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Odland (U.S.P.N. 5,989,498) in view of Clark, Jr. (U.S.P.N. 4,680,268) and further in view of Grabenkort (U.S.P.N. 5,143,617).

The teachings of the ('498) reference have previously been set forth with respect to claims 1-2, 5-9, 11, 14, 19 and 23-24, however; with respect to claim 17, the ('498) reference fails to teach the use ethylene oxide gas. The ('617) reference, which is in the art of sterilizing medical devices, teaches the use of ethylene oxide gas (col.6, lines 25-

28). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the ('498) reference to substitute ethylene gas ('617) for glutaraldehyde gas as taught by the ('268) reference since such a substitution between two well known gas sterilants is an obvious matter of routine experimentation.

10. Claims 26 and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipate by Clark, Jr. (U.S.P.N. 4,680,268).

With respect to claim 26, the ('268) reference a sterile implantable device (abstract, lines 1-3 and col.10, lines 27-35) that includes the following: a sterile electronic circuit (col.5, lines 53-57 and col.7, lines 58-68), biological molecule for use as an agent in generating a signal to be used by the sterile electronic circuit (col.7, lines 58-61) and a sterile reservoir (figure 1, 6).

With respect to claims 30-34, the ('268) reference teaches the following: the sterile biological molecule is a sensor matrix protein (col.10, lines 46-50), an integrated circle (col.7, lines 58-65 and col.8, lines 8-9), a polymer reservoir (col.6, lines 55-57), a permeable window covering the biological molecule (10) and the device can be used immediately (col.13, lines 47-50).

11. Claims 27-29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark, Jr. (U.S.P.N. 4,680,268) in view of Odland (U.S.P.N. 5,989,498).

The teachings of the ('268) reference have previously been set forth with respect to claims 26 and 30-34, however; with respect to claims 27-29 and 35, the ('268) reference fails to the use of an optically transmissive sterile package with a hydrated

biosensor within. With respect to claims 27-29 and 35, the ('498) reference discloses an optically transmissive sterile package with a hydrated sterile medical device within (col.5, lines 2). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of the ('268) reference by placing the biosensor in a sterile packaging as taught by the ('498) reference in order to maintain the physiological properties of implantable device.

Allowable Subject Matter

12. Claim 36 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

13. Claims 37-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1744

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji
Patent Examiner
AU 1744
09/21/2004

MRC


Terrence R. Tili
Primary Examiner